BIOTRONIK

# Eluna ProMRI FAQ

**1. Why do patients receive a pacemaker?**
Pacemakers are used to help patients whose heart rates are too slow, a condition known as bradycardia. A pacemaker delivers an electrical pulse to keep the heart beating at a normal rate, ensuring adequate blood and oxygen are delivered to the brain and other parts of the body.

**2. Why do patients need magnetic resonance imaging (MRI) scans?**
MRIs use high-energy magnetic fields and radio waves to create detailed images of the body's organs and structures. MRI images clearly depict body parts that are not seen as well with other imaging options such as X-ray, CT or ultrasound scans. MRI is especially helpful for diagnosing problems with joints, cartilage, ligaments and tendons, as well as problems with eyes, ears, heart and circulatory system.

An estimated 50 to 75 percent of patients with an implantable cardiac device (pacemaker or ICD) will need an MRI during their lifetime. [1]

**3. Why were pacemaker patients previously denied MRI scans?**
The strong forces applied during MRI scans may negatively affect both the leads and the device.
It is known that some metals respond to the strong magnetic fields and radiofrequency energy produced by MRI scans by absorbing and conducting heat. A lead incapable of dissipating all of this heat could cause damage to the heart or become ineffective at transmitting the heart signals that the device depends on.

In addition, pacemakers contain metallic and computerized components. As with leads, there was concern that MRIs could induce currents that would disable proper functionality of the device.

However, a series of multi-site clinical trials of BIOTRONIK's ProMRI technology has demonstrated that BIOTRONIK's pacemakers are safe for us in the MRI environment.

**4. How is Eluna ProMRI different from other pacemakers?**
Eluna ProMRI pacing system is FDA approved for use with all 1.5 T magnetic resonance imaging (MRI) scans. ProMRI technology allows patients to undergo full-body MRI scans with both single-chamber (SR-T) and dual-chamber (DR-T) Eluna pacemakers when implanted with Setrox pacing leads.

[1] Roguin et al., Europace (2008): 10, 336-346.

**5. What is the ProMRI® study?**
The ProMRI study is an ongoing investigation of BIOTRONIK MRI conditional devices. Current FDA approval includes full-body MRI scans for patients with the Eluna and Entovis devices when used with Setrox pacing leads. BIOTRONIK is the only company in the US with a complete portfolio of pacemakers approved for use with all 1.5 T MRI scans.

The ProMRI study also includes the investigation of implantable cardiac defibrillators (ICDs) in the MRI environment. The ProMRI ICD study is currently investigating the safety of BIOTRONIK ICDs, including the DX system, in patients undergoing full-body MRI scans. BIOTRONIK is one of only two companies in the U.S. currently approved to conduct these studies, which aim to broaden diagnostic options for cardiac device patients.

**6. Is Eluna ProMRI a first-of-its-kind technology?**
While there are other pacing devices commercially available that are approved for use in full-body MRI scans, BIOTRONIK's ProMRI family of products – which includes Eluna and Entovis pacing systems – are the only single- and dual-chamber pacemakers approved for use in full-body MRIs.

**7. How does the recent FDA approval affect the Entovis ProMRI pacing system?**
In May 2014, the Entovis pacemaker system with ProMRI technology was approved for use in the MRI environment with a limited exclusion zone. The recent FDA approval for Eluna ProMRI also extends to Entovis, which is included in the ProMRI family of products.